

Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (currently amended) A method for evaluating a clinical trial protocol specification, comprising the steps of:

~~encoding workflow tasks of a clinical trial protocol into a database that includes data objects describing protocol events and relationships among protocol events~~

encoding into a database, workflow tasks called for in a clinical trial protocol specification not yet in execution, including the step of encoding, into protocol specification objects of said database, specifications of protocol events that said protocol specifies to occur during execution of said protocol, and further including the step of encoding, into protocol specification objects of said database, relationships that said protocol specifies among said protocol events;

during said step of encoding workflow tasks called for in a clinical trial protocol specification not yet in execution, identifying an operational uncertainty in said protocol during said step of encoding in which said protocol specification contains at least one of the following deficiencies: said protocol specification fails to specify a particular parameter for use during protocol execution, or said protocol specification specifies such a parameter too vaguely to be encoded into said database, or said protocol specification specifies such a parameter inconsistently;

associating said uncertainty encoding into said database in association with at least a particular one of said protocol specification objects in said database, before execution of said clinical trial protocol, an indication that said operational uncertainty exists with respect to said particular object; and

in dependence upon protocol specification objects in said database, before execution of said clinical trial protocol, displaying a graphical-visual representation of said protocol, said graphical-visual representation including a human-perceptible indication that said particular protocol specification object has said operational uncertainty associated therewith.

2. (original) A method according to claim 1, wherein said database is an object-oriented database.

3. (currently amended) A method according to claim 1, wherein said dataprotocol specification objects include protocol event objects describing protocol events, and temporal constraint objects describing temporal constraints among said protocol event objects.

4. (currently amended) A method according to claim 3, wherein said step of displaying comprises the step of displaying each of said dataprotocol specification objects in a color which differs depending on whether an operational uncertainty is associated therewith.

5. (currently amended) A method according to claim 1, wherein said step of displaying comprises the step of displaying each of said dataprotocol specification objects in a color which differs depending on whether an operational uncertainty is associated therewith.

6. (currently amended) A method according to claim 1, wherein said operational uncertainty comprises an inconsistency in said protocol specification.

7. (currently amended) A method according to claim 1, wherein said operational uncertainty comprises an insufficiently specified parameter in said protocol specification.

8. (currently amended) A method according to claim 1, wherein said operational uncertainty comprises an omitted parameter in said protocol specification.

9. (original) A method according to claim 1, wherein said operational uncertainty concerns a temporal constraint among at least two of said protocol events.

10. (currently amended) ~~At a set of at least one computer readable medium collectively,~~
said set carrying a machine readable database which includes protocol dataspecification objects describing protocol events ~~of that a clinical trial protocol and relationships among protocol~~

eventsspecification specifies to occur during execution of the elinical trialsaid protocol, and relationships among said protocol events.

said database further including a disambiguation comment object which identifies an operational uncertainty in which said protocol specification contains at least one of the following deficiencies: said protocol specification fails to specify a parameter for use during protocol execution, or said protocol specification specifies such a parameter too vaguely to be encoded into said database, or said protocol specification specifies such a parameter inconsistently, said disambiguation comment object being associated with at least a particular one of said objects in said database.

11. (original) A medium according to claim 10, wherein said database is an object-oriented database.

12. (currently amended) A medium according to claim 10, wherein said ~~dataprotocol~~ specification objects include protocol event objects describing protocol events, and temporal constraint objects describing temporal constraints among said protocol event objects.

13. (original) A medium according to claim 12, wherein said disambiguation comment object is associated with one of said protocol event objects.

14. (original) A medium according to claim 12, wherein said disambiguation comment object is associated with a particular one of said temporal constraint objects.

15. (original) A medium according to claim 14, wherein said operational uncertainty concerns the amount of time allowed to elapse between two protocol events identified by said particular temporal constraint object.

16. (currently amended) A medium according to claim 12, wherein said ~~dataprotocol~~ specification objects further include workflow task objects.

17. (original) A medium according to claim 16, wherein each of said workflow task objects is associated with at least one of said protocol event objects.

18. (original) A medium according to claim 16, wherein said disambiguation comment object is associated with one of said workflow task objects.

19. (currently amended) A medium according to claim 10, wherein said operational uncertainty comprises an inconsistency in said protocol specification.

20. (currently amended) A medium according to claim 10, wherein said operational uncertainty comprises an insufficiently specified parameter in said protocol specification.

21. (currently amended) A medium according to claim 10, wherein said operational uncertainty comprises an omitted parameter in said protocol specification.

22. (original) A medium according to claim 10, wherein said operational uncertainty concerns the amount of time allowed to elapse between two of said protocol events.

23. (currently amended) ~~At A set of at least one computer readable medium collectively,~~
the set carrying a plurality of machine readable database which includes protocol event objects
~~describing events of objects instantiated according to a clinical trial pre-specified class structure,~~
the machine readable objects including protocol event specification objects describing protocol
events that a protocol specification specifies to occur during execution of said protocol, and
temporal constraint specification objects describing temporal relationships that a protocol
specification specifies to occur among protocol events described in said protocol event
specification objects, at least a particular one of said temporal constraint specification objects
identifying an amount of time that said protocol specifies is to elapse between at least two of
said or more protocol events when the protocol is executed.

24. (currently amended) A medium according to claim 23, wherein said ~~database is~~ plurality of machine readable objects are objects of an object-oriented database.

25. (currently amended) A medium according to claim 23, wherein said ~~database~~plurality of machine readable objects further includes workflow task objects.

26. (currently amended) A medium according to claim 23, wherein said amount of time describes the time that a hypothetical patient is expected to take between protocol events described in first and second identified ones of said protocol event objects.

27. (original) A medium according to claim 23, wherein said particular temporal constraint object identifies said amount of time by identifying at least one member of the group consisting of minimum and maximum times.

28. (original) A medium according to claim 27, wherein said particular temporal constraint object identifies said amount of time by identifying both members of the group consisting of minimum and maximum times.

29. (original) A medium according to claim 28, wherein said particular temporal constraint object identifies said amount of time further by identifying a base time between said minimum and maximum times.

30. (currently amended) A medium according to claim 23, wherein said ~~database~~plurality of machine readable objects further includes a disambiguation comment object associated with said particular temporal constraint object, said disambiguation comment object identifying an operational uncertainty in a particular temporal relationship identified in said temporal constraint object.

31. (currently amended) A medium according to claim 23, wherein said operational uncertainty comprises an inconsistency in one of said temporal relationships as specified in said protocol specification.

32. (currently amended) A medium according to claim 23, wherein said operational uncertainty comprises vagueness in one of said temporal relationships as specified in said protocol specification.

33. (currently amended) A medium according to claim 23, wherein said operational uncertainty comprises omission of one of said temporal relationships from said protocol specification.

34. (currently amended) A method for evaluating a clinical trial protocol specification, comprising the steps of:

encoding into a database, workflow tasks of called for in a clinical trial protocol into a database specification not yet in execution, said database being structured according to a predetermined model, said model including slots predefined for describing respective aspects of protocol events and that a protocol can specify to occur during execution of the protocol, said model further including slots predefined for describing temporal relationships that a protocol can specify among such protocol events, said slots predefined for describing temporal relationships including slots predefined for describing amounts of time allowed that a protocol specifies are to elapse between two or more protocol events; and

during said step of encoding, identifying an operational uncertainty in which said protocol regarding a particular specification contains at least one of the following deficiencies: said amounts-protocol specification fails to specify an amount of time that is to elapse between two or more protocol events, or said protocol specification specifies such an amount of time too vaguely to be encoded into said database, or said protocol specification specifies such an amount of time inconsistently.

35. (original) A method according to claim 34, further comprising the step of displaying a graphical-visual representation of said protocol, said graphical-visual representation including a human-perceptible indication that said particular amount of time has an operational uncertainty associated therewith.

36. (currently amended) A method according to claim 34, wherein said predetermined model comprises a predetermined object class structure and said slots are organized into dataprotocol specification objects defined by said object class structure.

37. (currently amended) A method according to claim 36, wherein said dataprotocol specification objects include protocol event objects describing protocol events, and temporal constraint objects describing temporal constraints among events described in said protocol event objects, each of said temporal constraint objects including at least one slot for identifying an amount of time allowed between two or more protocol events.

38. (currently amended) A method according to claim 37, further comprising the steps of:
instantiating a disambiguation dataprotocol specification object defined according to said object class structure describing said operational uncertainty; and
associating said disambiguation dataprotocol specification object with a temporal constraint object which includes a slot for identifying said particular amount of time.

39. (currently amended) ~~A medium~~ A method according to claim 34, wherein said operational uncertainty comprises an inconsistency in said particular amount of time as specified in said protocol specification.

40. (currently amended) ~~A medium~~ method according to claim 34, wherein said operational uncertainty comprises vagueness in said particular amount of time as specified in said protocol specification.

41. (currently amended) A ~~medium-method~~ according to claim 34, wherein said operational uncertainty comprises omission of said particular amount of time from said protocol specification.

42. (currently amended) A method for evaluating a clinical trial protocol specification, comprising the steps of:

~~encoding workflow tasks of a clinical trial protocol into a database that includes data objects describing protocol events and relationships among protocol events;~~

encoding into a database, workflow tasks called for in a clinical trial protocol specification not yet in execution, including the step of encoding, into protocol specification objects of said database, specifications of protocol events that the protocol specifies to occur during execution of the protocol, and further including the step of encoding, into protocol specification objects of said database, relationships that the protocol specifies among said protocol events;

during said step of encoding workflow tasks called for in a clinical trial protocol specification not yet in execution, identifying an operational uncertainty in said protocol during said step of encoding in which said protocol specification contains at least one of the following deficiencies: said protocol specification fails to specify a parameter for use during protocol execution, or said protocol specification specifies such a parameter too vaguely to be encoded into said database, or said protocol specification specifies such a parameter inconsistently;

encoding said uncertainty into said database in association with at least a particular one of said protocol specification objects in said database, before execution of said clinical trial protocol, an indication that said operational uncertainty exists with respect to the particular protocol specification object; and

in dependence upon objects in said database, before execution of said clinical trial protocol, outputting a report setting forth the operational uncertainties identified in said protocol and encoded into said database.

43. (currently amended) A method according to claim 42, further comprising the step of associating said particular ~~data~~ protocol specification object with at least one of said ~~data~~ protocol specification objects in said database.

44. (currently amended) A method according to claim 43, wherein said ~~data~~protocol specification objects include protocol event objects describing protocol events, and temporal constraint objects describing temporal constraints among protocol events described in said protocol event objects,

and wherein said step of associating comprises the step of associating said particular ~~data~~ protocol specification object with one of said protocol event objects or one of said temporal constraint objects in said database.

45. (original) A method according to claim 42, wherein said database is an object-oriented database.

46. (original) A method according to claim 42, further comprising the step, prior to said step of outputting, of sorting a list of said operational uncertainties identified in said protocol and encoded into said database.

47. (original) A method according to claim 42, wherein said step of outputting comprises the step of outputting in tabular form the operational uncertainties identified in said protocol and encoded into said database.

48. (currently amended) A method according to claim 42, wherein said operational uncertainty comprises an inconsistency in said protocol specification.

49. (currently amended) A method according to claim 42, wherein said operational uncertainty comprises an insufficiently specified parameter in said protocol specification.

50. (currently amended) A method according to claim 42, wherein said operational uncertainty comprises an omitted parameter in said protocol specification.

51. (currently amended) A method according to claim 42, wherein said operational uncertainty concerns a temporal constraint among at least two of said protocol events specification.

///